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10/690,404	10/21/2003	Hiroki Moriyama	17136	5953

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EXAMINER	
KASZTEJNA, MATTHEW JOHN	
ART UNIT	PAPER NUMBER
3739	
MAIL DATE	DELIVERY MODE
08/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,404	MORIYAMA, HIROKI	
	Examiner	Art Unit	
	MATTHEW J. KASZTEJNA	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/27/8, 3/17/8*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 25, 2008 has been entered.

Notice of Amendment

In response to the amendment filed on June 25, 2008, amended claims 1 and 17 and new claim 19 are acknowledged. The current rejections of claims 1-18 *stand.* The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,690,175 to Ouchi et al. in view of U.S. Patent No. 5,916,147 to Boury.

In regards to claims 1-4 and 17, Ouchi et al. a flexible tube for use in an endoscope comprising: an insertion unit having a soft portion; a small-diameter portion

3c which is included in the soft portion and whose outer diameter is *substantially* the same over the whole length thereof; a large-diameter portion 3f which is formed on the operator side of the soft portion opposite the small-diameter portion and whose outer diameter is larger than the outer diameter of the small-diameter portion; and a tapered portion 3d-e linking the small-diameter portion and the large-diameter portion, and a sheathing resin that is an integral member having a thickness which is varied in order to form the small-diameter portion, the large-diameter portion and the tapered portion (see Fig. 5 and Col. 7, Lines 9-35). Furthermore, Ouchi et al. teach of a flexible tube relating generally to flexible tubes for endoscopic devices having improved flexibility, torsional rigidity and resistance to compression for facilitating insertion of the tube into the body cavity but are silent with respect to the insertion portion having an articulating section at the distal end of the endoscope and a control section disposed at the proximal end of the insertion unit for controlling articulation of the articulating section. Ouchi et al. teach of a manipulating unit at the proximal end of the apparatus (see Col. 7, Lines 48-52) but are silent with respect to the unit being used specifically for controlling the articulating section of the insertion unit. Boury teaches of an analogous apparatus comprising a catheter which can be manipulated by a physician even after the catheter is placed into the patient's body. The catheter includes an elongate tubular member which has a proximal end, a distal end, a remotely manipulable length, and a wall defining a lumen. The catheter also includes first and second wires slidably retained by the wall and extending proximally beyond the proximal end of the tubular member. The first wire is attached adjacent a distal end thereof to the wall at a first node located along the

manipulable length. The second wire is attached adjacent a distal end thereof to the wall at a second node located along the manipulable length, with the second node being located distally of the first node along the manipulable length of the tubular member (see Figs. 1-3 and Col. 2, Line 53 – Col. 3, Line 25). Boury demonstrates that it is well known within the art to provide endoscopic devices with control means to facilitate insertion of the flexible tube within the body. Thus, It would have been obvious to one skilled in the art at the time the invention was made to provide the apparatus of Ouchi et al. with an articulating section and a control section to control the insertion section, thus allowing a physician to shape a length of the tube and to permit it to be more readily positioned within a body channel of the patient as taught by Boury and is well known within the art. Furthermore, Boury teaches that the overall length of the insertion tube may be varied as necessary, from 50-150 cm (see Col. 4, Lines 6-20). Thus the tapered portion would be located forward an endoscope portion located 45cm from the distal end.

In regards to claim 18, Ouchi et al. a flexible tube for use in an endoscope, wherein the thickness of the sheathing resin is varied in order to form the small-diameter portion 3c, the large-diameter portion 3f, and the tapered portion 3d-e; and the sheathing resin has an inner diameter formed to be constant over the small-diameter portion, the large-diameter portion, and the tapered portion (see Fig. 5 and Col. 7, Lines 10-15). As seen in figure 5, the inner diameter (not labeled) is clearly a constant diameter over the length of the tube.

Claims 5-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,690,175 to Ouchi et al. in view of U.S. Patent No. 5,916,147 to Boury in further view of U.S. Patent No. 5,084,022 to Claude.

In regards to claims 5-8, Ouchi et al. and Boury disclose an apparatus having an articulating section, a control section and large and small diameter portions connected via a tapered portion (see above rejection) but are silent with respect to indices indicating distances from the distal end are inscribed on the soft portion and the specifics of where indices may be inscribed along the soft portion. Claude teaches of an analogous medical apparatus provided with spaced indicia to indicate the distance the instrument is extended into a vascular vessel, catheter or other instrument (see Figs. 1-3 and 6). **In regard to claims 9-12**, Claude teaches of an apparatus wherein the indices are inscribed equidistantly along the apparatus (see Col. 2, Lines 33-36). **In regard to claims 13-16,** the indices may be formed on the instrument in any desired location considered to be helpful to the operator and the desired procedure and may be formed over the entire length of the apparatus (see Figs 4-5 and Col. 5, Lines 1-9). It would have been obvious to one skilled in the art at the time the invention was made to include indices on the apparatus of Ouchi et al. and Boury in order to facilitate the determination of the distance an instrument extends into a cavity as taught by Claude.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,690,175 to Ouchi et al. in view of U.S. Patent No. 5,916,147 to Boury in further view of U.S. Patent No. 5,083,549 to Cho et al.

In regards to claim 19, Ouchi et al. and Boury disclose an apparatus having an articulating section, a control section and large and small diameter portions connected via a tapered portion (see above rejection). Ouchi et al. teach of tube having uniform inner diameters and wall thicknesses (See Fig. 2) and of a tube structure with a constant inner diameter and a wall thickness which varies from one end to the other (see Fig. 5), but fails to specifically teach of a tube wherein the small-diameter portion and the large diameter portion each have a *substantially* constant outer diameter over their respective length. Cho et al. teach of an analogous apparatus having an endoscope shaft which changes in thickness and is preferably in stages 19, 21, 23 of different constant outside diameter. Stages 19, 21, 23 each have different outside diameters that are constant over their entire length, with the most distal end having the smallest outside diameter and the most proximal end having the largest outside diameter (see Fig. 2 and Col. 5, Lines 1-10). Furthermore, Figs. 5a and 5b show two possible combinations of the step-tapered and the uniformly tapered design concepts. In FIG. 5a, the shaft 60 has a proximal step portion 62 of constant outside diameter, connected to a uniformly tapered distal portion 66. FIG. 5b shows a shaft 68 with a uniformly tapered proximal end 70 connected to a distal stage 72 of constant outer diameter. It is apparent that a number of different combinations of shaft portions are possible, and the preferred embodiments described are for illustration only (see Col. 5, Lines 57-67). It would have been obvious to one skilled in the art at the time the invention was made to provide the small-diameter and large-diameter sections in the apparatus of Ouchi et al. and Boury with a constant diameter to provide an alternative

embodiment wherein the varying outer diameter of the endoscope dilates canals into which the endoscope is inserted. The thin distal end penetrates and dilates subject body canals to a degree which allows the wider portions of the device to easily follow. Ultimately, such design allows for dilation that is gradual and hence less traumatic than with existing devices as taught by Cho et al.

Response to Arguments

Applicant's arguments filed June 25, 2008 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a single integral sheathing resin) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant further argues that the sheathing resin of Ouchi et al. is not formed integrally but divided section by section and thus fails to disclose a sheathing resin that is an integral member having a thickness which is varied. Examiner disagrees. Ouchi et al. teach that sections 33c-f are integrally bonded to form a single integral member, resulting in a continuous seamless outer surface (see Col. 7, Lines 20-35). It is an objective of Ouchi et al. to fuse the segments together and integrally bond them to the tubular core structure to ensure a flexible tube having a smooth outer surface which can

be flexed in conformity with a curved path presented by the organ within the body cavity (see Coll. 87, Lines 15-20).

Furthermore, the term "integral" is sufficiently broad to embrace constructions united by such means as fastening and welding (in re Hotte (C.C.P.A.) 157 U.S.P.Q. 326); the term is not necessarily restricted to a one-piece article (in re Kohno (C.C.P.A.) 157 U.S.P.Q. 275); and may be construed as relatively broad (in re Dike (C.C.P.A.) 157 U.S.P.Q. 581). By definition integral means, consisting or composed of parts that together constitute a whole (see http://dictionary.reference.com/browse/integral). Thus, as broadly as claimed, the sheathing of Ouchi et al. meets the current limitations of the instant invention as it is an integral member having a thickness which is varied.

Applicant's arguments with respect to claim 19 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. K./
Examiner, Art Unit 3739

8/1/8